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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,300	10/26/2001	Steven E. Ealick	UAB-20702/22	2920

7590

04/26/2005

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EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/035,300

Applicant(s)

EALICK ET AL.

Examiner

Jon Eric Angell

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 54 and 56.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 2, 6, 7 and 9-33.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): _____.
13. ☒ Other: See Continuation Sheet.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER

Jon Eric Angell *JA*

Continuation of 3. NOTE: New claim 57 is drawn to an isolated nucleotide sequence comprising a coding sequence for a full-length mutant E. coli purine nucleoside phosphorylase (PNP) having an amino acid substitution mutation selected from the group consisting of M65V A157L, A157L, E180D, M65A and D205N, the mutant E. coli purine nucleoside phosphorylase having different biological activity than a wild type microbial purine nucleoside phosphorylase. The proposed claim 57 encompasses any mutant full length E. coli PNP that has one of the indicated substitutions and has a different biological activity than a wild type microbial PNP. The claim is not limited to any specific mutations of SEQ ID NO: 2; rather the claim broadly encompasses any mutant E. coli PNP having the indicated mutations— such as mutants comprising substitutions of any or all amino acids (i.e., 1-239 of SEQ ID NO: 2) wherein the mutant PNP comprises 1 of the 6 specific claimed substitutions. Therefore, the new claims would introduce limitations that require new search and considerations, including considerations with respect to written description and enablement of the mutant PNPs encompassed by the claim. Furthermore, proposed claim 57 indicates that the mutant E. coli PNP has a different biological activity than a wild type "microbial" PNP. Therefore, the mutant PNPs can have completely different biological activity than the wild type PNP including non-functional mutant PNPs. This raises enablement issues with respect to the non-functional mutant PNPs encompassed by the claims. Furthermore, the claim indicates that the mutant "E. coli" PNP has a different biological activity than wild type "microbial" PNP. The discrepancy between the recitation of "E. coli" PNP in the preamble and "microbial" PNP in the final two lines of the claim raise issues under 35 USC 112, first and second paragraphs, as microbial PNP is broader in scope than E.coli PNP. Therefore, the claim encompasses the mutant E. coli PNPs wherein the mutant E. coli PNP has a biological activity different from a microbial PNP (i.e., any microbial PNP), but not necessarily different from wild type E. coli PNP.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments are with respect to the proposed amended claims. However, the proposed claims have not been entered. Therefore, Applicants arguments are not persuasive and the rejections of record stand. With respect to Applicants arguments that the M65A and D205N mutants have activity, as indicated in Tables I and II, it is acknowledged that Table II does supply data indicating PNP activity of M65A. However, the argument that Table I indicates that the mutants have activity greater than negative control is not persuasive. It was pointed in the rejection that Table I only indicated that the 4 specific mutants had biological activity that was "significantly greater than negative control". When considering that the positive control is designated 100% activity and negative control is designated 0.8% (for MeP-dR) and 3% (for F-araA) the disclosure that D205N has 2.2% activity for MeP-dR and 2.4% activity for F-araA is not considered significantly greater than the negative control. It is also respectfully pointed out that the specification acknowledges, "Of the 22 mutants of Table I, M65V, A157L, A157V and E180D retained some appreciable activity" (see page 11, lines 5-7 of the specification) which is consistent with the Examiner's position that Table I only shows significant biological activity for the M65V, A157L, A157V and E180D mutants.

Continuation of 13. Other: The Examiner would like to thank Applicants for pointing out the typographical error that incorrectly on the Office Action Summary which indicates that claims 54 and 55 are rejected. Claim 55 was previously cancelled; therefore, the claim is not rejected. Claim 54 is considered allowed, as indicated in the Office Action. Claim 54 was inadvertently indicated as rejected on the Office Action Summary.

